

REMARKS

Reconsideration and withdrawal of the objections to the drawings and claims, and rejections of the claims, in view of the remarks and amendments herein, is respectfully requested. Claims 1, 3, 12, 14-15, 23, 25, 33-34, 40-41, 43-44, 47, 49-50, 52, 55-56, 65, and 69 are amended, claims 13 and 57-62 are canceled, and claims 70-73 are added; as a result, claims 1-12, 14-56, 63-67, and 69-73 are now pending in this application. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims present prior to amendment, which claims are in a continuing application of the above-identified pending application.

Enclosed are corrected drawings which address the objections on page 3 of the Office Action.

Claim 40 was objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 25, 40 and 41 were objected to because they depend from claim 2, which has been withdrawn from examination. The amendment to claims 25 and 41 to delete "2", and to claim 40 to delete "1" and "or 3", moot these objections.

The 35 U.S.C. § 112, Second Paragraph, Rejection

Claims 14-15, 34-36, 43, 50-52, 55-56, 65-67, and 69 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The amendments to claims 14-15, 34, 43, 47, 50, 52, 55-56, 65, and 69, to delete "Triton® X-100" and "Tween®20" or "functional equivalent thereof", obviate the § 112(2) rejections. Therefore, withdrawal of the § 112(2) rejections is respectfully requested.

The 35 U.S.C. § 112, First Paragraph, Rejection

Claims 14-15, 43, 47, 50-52, 55-56, 65-67, and 69 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate enablement. This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

In particular, the Examiner asserts the specification, while being enabling for a method for determining luminescence energy produced by a first and second luciferase-mediated

luminescence reaction, wherein at least one of the luciferases is anthozoan and the luminescence generated by the anthozoan luciferase is selectively quenched by coelenterazine hh methyl ester, colored compounds that absorb red, yellow, green and blue wavelengths of light as disclosed on page 31, lines 11-19 of the specification, and nonionic detergents, and a kit therefor, does not reasonably provide enablement for a method or kit wherein the first enzyme mediated reaction is provided by any non-beetle luciferase or the selective quenching of the first enzyme mediated reaction is by any possible substrate analog inhibitor for an anthozoan luciferase or a protected coelenterazine or any possible colored compound.

Given Applicant's disclosure that substrate analog inhibitors of luminescence reactions, nonionic detergents and certain colored compounds can inhibit luminescence mediated by enzymes such as an anthozoan luciferase or a peroxidase without substantially inhibiting a subsequent luminescence reaction, i.e., those agents are selective quench reagents, it is within the skill of the art to identify specific substrate analog inhibitors, specific nonionic detergents and specific colored compounds other than those in the working examples in the specification, that are selective quench reagents for an anthozoan luciferase- or peroxidase-mediated luminescence reaction. Evidence that identifying selective quench reagents is within the skill of the art is provided by Sherf et al. (U.S. Patent No. 5,744,320), a reference cited against the claims under § 102(b)/§ 103.

Therefore, withdrawal of the § 112(1) rejection is respectfully requested.

The 35 U.S.C. § 102 Rejection

Claims 1, 3, 6-8, 12-13, 22-24, 32-36, 38-42, 44, 49, and 54 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sherf et al. (U.S. Patent No. 5,744,320). This rejection is respectfully traversed.

Sherf et al. generally disclose dual luminescence reporter assays. It is disclosed that implicit to the concept of an integrated (i.e., sequential-measurement) dual-enzyme reporter assay is the necessity to efficiently quench luminescence from the first reporter enzyme such that the activity of the second luminescent reporter is not inhibited (column 17, lines 33-37). Table 1 in Sherf et al. discloses general quench reagents for firefly luciferase and Table 2 in Sherf et al. discloses general quench reagents for *Renilla* luciferase. The only data disclosing reagents

useful to quench one reaction without substantially quenching a subsequent reaction are shown in Tables 4 and 5 (a "selective" quench reagent) and that data relates to reagents that quench a firefly luciferase-mediated reaction without substantially quenching a subsequence *Renilla* luciferase reaction.

The standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its elements. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q.2d 90 (Fed. Cir. 1986); In re Dillon, 16 U.S.P.Q.2d 1987 (Fed. Cir. 1990).

Sherf et al. do not disclose or suggest a method which employs, or kits having, at least one selective quench reagent for an anthozoan luciferase- or peroxidase-mediated luminescence reaction, e.g., a selective quench reagent that quenches that reaction by at least 35-fold without substantially quenching a subsequent luminescence reaction.

In response to the Examiner's assertion that a firefly such as *Photinus pyralis* is not a beetle (page 4 of the Office Action), the Examiner is requested to consider page 2, line 4 of the specification and the abstract for Branchini et al. (Biochemistry, 43:7255 (2004), a copy of which is enclosed herewith)). Fireflies are nocturnal, luminescent beetles of the beetle family *Lampyridae* (order *Coeloptera*).

Accordingly, withdrawal of the § 102(b) rejection is respectfully requested.

The 35 U.S.C. § 103 Rejections

Claims 14-15, 43, 47, 50-52, 55, 56, 65-67, and 69 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sherf et al. (U.S. Patent No. 5,744,320) in view of The Sigma Catalog (1998). This rejection is respectfully traversed.

It is the Examiner's position that in view of the Sigma Catalog, which discloses a list of 27 nonionic detergents for biological applications, it would have been obvious to one of ordinary skill in the art at the time the invention was made to test any of the 27 detergents disclosed by Sigma in the method or kit as taught by Sherf. The Examiner continues asserting that an ordinary artisan would have been motivated to do so because Sigma sells additional nonionic detergents that may have an equal or better effect than Tween®20 or Triton®X-100, and thus the ordinary artisan would have realized that nonionic detergents have the same mechanism of

sequestration and the testing of a limited number of nonionic detergents (that are easily obtained) would serve to optimize the selective quenching step of the assay.

There is nothing in Sherf et al. or the Sigma Catalog, alone or in combination, which discloses or suggests an agent that selectively quenches an anthozoan luciferase-mediated reaction, e.g., by at least 35-fold, yet allows for a different luminescence reaction.

Thus, withdrawal of the § 103 rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

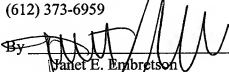
Respectfully submitted,

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Date

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 9th day of April 2008.

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